Surgical Patterns of Care in Operable Lung Carcinoma Treated with Radiation

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Purpose: To determine the national surgical practice patterns of care for operable lung cancer patients treated with radiation.

Materials and Methods: A nationwide survey of a stratified random sample of institutions was conducted for patients who had non-metastatic lung cancer, Karnofsky Performance Scores (KPS) ≥60, and who had received radiation therapy as definitive or adjuvant treatment. Among 541 patients, representing a weighted sample size of 42,335 patients nationwide, 131 (19.8%) underwent surgery as part of their therapy. Pearson χ^2 statistics were used to analyze characteristics of this subset of patients.

Results: Of the 131 patients who underwent surgery, 126 patients who had non-small cell lung cancer (NSCLC) were analyzed. Surgical patients were younger, had less weight loss, higher KPS, and higher forced expiratory volume within 1 second (FEV1) values than those treated without surgery. Surgical patients had more stage I/II (53.5% vs 32.2%; $p = 0.0004$) and less clinical N2/N3 disease (28.8% vs 47.5%; $p = 0.002$) than nonsurgical patients. Surgery consisted of lobectomy or bilobectomy in 63.2% of patients, pneumonectomy in 23.5%, and wedge resection in 5.9%. Of the patients, 80.4% received radiation in the adjuvant setting and 9.9% in the neoadjuvant setting.

Conclusions: Patients with non-metastatic lung cancer who are treated surgically and with radiation have clinically less advanced disease than those treated with radiation alone. Most radiation therapy in this setting is administrated postoperatively and secondary to hilar and/or mediastinal nodal involvement undetected before surgery. Improved preoperative nodal staging and neoadjuvant approaches may alter these practice patterns.

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The Patterns-of-Care Study (PCS) has emerged as a unique method of assessing national practice patterns associated with a variety of cancers. Reports on the use of radiation in the treatment of prostate, breast, and colon cancers have revealed the correspondence between recommended and actual treatment.[1–3] Given the enormous impact of lung cancer on the population, the PCS model was recently applied to it.

Lung cancer remains the number one cause of cancer death in the United States. It is estimated that it will cause 162,460 deaths in 2006,[4] more than the number of deaths from breast, prostate, and colorectal cancers combined. Non-small cell lung cancer (NSCLC) accounts for approximately 80% to 85% of lung cancer cases, and small cell lung cancer (SCLC) accounts for the remainder. Despite increased research and improvements in combined modality treatments, the prognosis for lung cancer patients remains dismal. The overall 5-year survival rate for 1995 to 2001 was only 15.3%.[5]

In 2003, the results of the first PCS involving radiation therapy for lung cancer were published.[6] Later, the same data set was analyzed to specifically examine the use of chemotherapy.[7] These analyses summarized practice patterns in patients treated with radiation for NSCLC and SCLC in 1998 and 1999 in a wide array of care facilities. One goal of these studies was to determine whether results of positive clinical trials were being incorporated into routine practice. At the time, reports of randomized clinical trials[8] and meta-analyses[9] supported the use of combined chemotherapy and radiation compared with radiation alone. The results of the PCS analyses[6,7] showed that combined modality treatment had been adopted and was typically used in the care of limited stage SCLC and locally advanced NSCLC. It was concluded that current practice in the United States generally matched evidence-based literature recommendations for locally advanced disease.

We revisited the PCS data set[6,7] to analyze the use of surgery among patients treated with radiation therapy. Specifically, we analyzed the type of surgery, nodal staging, completeness of resection, and timing of radiation with re-

spect to surgery. We also reviewed the effects of race, age, gender, co-morbidities, and other non-clinical factors on patients who received surgery.

PATIENTS AND METHODS

Patient Population:

To select representative patients of the total population, we used a stratified two-stage sampling design to choose centers and patients for data collection. A comprehensive list of radiation therapy facilities in the United States were stratified into three groups: academic centers (including the main teaching hospitals of medical schools or National Cancer Institute comprehensive cancer center designees), large non-academic facilities (including centers that treat 500 or more new radiation therapy patients per year), and small non-academic facilities (including those treating fewer than 500 new radiation-therapy patients per year). The sample was then drawn independently from each group (stratum). Eighty facilities were randomly selected from the three strata and invited to participate in the survey, although two of those facilities closed before the survey began. Data were collected at on-site chart reviews in 2000 to 2002 by PCS research employees at 22 academic centers, 19 large nonacademic centers, and 18 small non-academic centers, for a participation rate of 76%. In the second stage of sampling, cases of lung cancer were randomly selected for further data review and abstraction based on lists provided by each selected facility according to standard eligibility criteria.

To be eligible for retrospective review in this study, each patient had to meet several criteria: treatment administered during 1998 and 1999, AJCC 1997 nonmetastatic lung cancer (stages I-III), use of radiation for definitive or adjuvant treatment, and a Karnofsky performance score (KPS) of at least 60. On the basis of those criteria, a weighted sample size (wss) of 42,355 patients was gleaned, and 541 patient records were individually reviewed by PCS-trained researchers. The detailed analysis included information regarding patient demographics, staging, and treatment. Of the 541 patients, 131 representing 8398 (wss) underwent surgery as part of their therapy. Among 131 surgical patients, 126 (representing 8214) had NSCLC.

Statistical Analysis

National estimates were calculated from the survey data using SUDAAN statistical software (Research Triangle Institute, Research Triangle Park, NC), which incorporates the design elements (two stages of stratification) and weights that reflect the relative contribution of each institution and each patient in the analysis of this complex survey. The weights were the product of the following two factors:

All figures calculated using SUDAAN were national estimates for the patient population defined by the eligibility criteria. Tests for association were performed using the Pearson χ^2 statistic in SUDAAN. Differences were deemed significant if the associated p values were <0.05. Details of surgical resection, nodal staging, completeness of resection, and timing of radiation therapy and chemotherapy with respect to surgery were specifically investigated.

RESULTS

The patient and tumor characteristics of the entire study population were analyzed. The median age at the time of radiation therapy was 67 years (range, 29 to 92 years). The population was 61% male and 39% female. Only 3.9% of the patients were never-smokers, and 38% were active smokers at the time of treatment. Approximately 83% of the patients had KPS of 80 or greater, and 61% had a co-morbidity identified in their medical histories. Approximately 85.5% of patients had a diagnosis of NSCLC, and 14.5% had a diagnosis of SCLC, as estimated from wss. Those proportions are consistent with expected distribution from SEER database studies.[5] The clinical stage distribution was 15.4%, 18.5%, 58.3%, and 7.8% for stage I, stage II, stage III, and unknown, respectively.

With regard to staging, 97.8% of all patients had chest computed tomographic (CT) scans, 56.1% had bone scans, and 2.6% had positron-emission tomographic (PET) scans. For evaluation of brain metastases, 38.8% had brain CT scans, and 11.0% had brain magnetic resonance imaging (MRI). Of the NSCLC surgical patients, 50.9% had pathologic staging of the mediastinum; among them, 20.6% had a transbronchial nodal biopsy for staging, 56.5% had mediastinoscopy, 16.3% had anterior mediastinotomy, and a 1.1% had a video-assisted thoracic procedure.

Overall, 19.8% of the study population underwent surgery. Of the surgical patients, 97.8% had NSCLC compared with 85.5% of the overall population. These patients with NSCLC are the focus of the remainder of the analysis, and the relationship between specific patient characteristics and the use of surgery in NSCLC is shown in Table 1. Of these, the patients treated who underwent surgery were younger than those who did not (mean age, 60.6 versus 68.9 years; $p < 0.0001$). They also tended to have higher performance status: 93.4% had KPS of 80 or greater versus 79% of nonsurgical patients ($p = 0.001$). Surgical patients also had higher FEV1 measurements; 20.3% of surgical patients had FEV1 greater than 2 L versus 3.3% of nonsurgical patients ($p = 0.03$). Finally, fewer surgical patients than nonsurgical patients had pretreatment weight loss of more than 5% (14% versus 26%; $p = 0.06$). There were no statistical differences in previously identified co-morbidities, race, or gender between the surgical and nonsurgical groups.

The relationship between disease characteristics and use of surgery in NSCLC is shown in Table 2. There was no statistically significant difference between surgical and nonsurgical patients in clinical T stages. However, surgical patients had more clinical stage I/II (53.5% versus 32.2%; $p = 0.0004$) and less clinical N2/N3 disease (28.8% versus 47.5%; $p = 0.002$) than nonsurgical patients. The final pathological stage in surgical patients is listed in Table 2. The details of the surgical procedures are listed in Table 3. Surgery consisted of lobectomy or bilobectomy in 63.2% of patients, pneumonectomy in 23.5%, wedge resection in 5.9%, exploration alone (no resection) for 11.1%, and unknown surgery type for 1.1%. For patients who underwent surgery, pathological staging was 9.5% stage I, 35.9% stage II, 45.1% stage III, and 9.5% unknown, according to AJCC 1997

TABLE 1. Pretreatment patient characteristics and use of surgery

Characteristic	Received surgery		Did not receive surgery	
	Weighted sample size (unweighted)	Percentage[a]	Weighted sample size (unweighted)	Percentage[a]
Total	8,214 (126)	22.7	27,983 (343)	77.3
Age (yr)[b] ($p = 0.0004$)				
<70	6,443 (91)	78.4	13,504 (180)	48.3
≥70	1,771 (35)	21.6	14,446 (162)	51.7
Sex ($p = 0.9870$)				
Male	5,150 (74)	62.7	17,517 (204)	62.6
Female	3,064 (52)	37.3	10,466 (139)	37.4
Race ($p = 0.6184$)				
Caucasian	6,639 (107)	80.8	22,418 (256)	80.1
Black / African-American	1,264 (13)	15.4	4,878 (70)	17.4
Hispanic / Latino	89 (4)	1.1	271 (7)	1.0
Asian	222 (2)	2.7	65 (5)	0.2
Other	0	0	351 (5)	1.3
KPS ($p = 0.0186$)				
60	0	0	1,171 (15)	4.2
70	541 (7)	6.6	4,672 (51)	16.7
80	3,102 (46)	37.8	12,103 (164)	43.3
90	3,980 (67)	48.5	9,297 (103)	33.2
100	590 (6)	7.2	709 (9)	2.5
Unknown	0	0	31 (1)	0.1
Co-morbidity ($p = 0.8105$)				
Yes	4,668 (62)	56.8	17,004 (214)	60.8
No	3,312 (62)	40.3	10,351 (121)	37.0
Unknown	234 (2)	2.9	629 (8)	2.2
Weight loss >5% ($p = 0.0940$)				
Yes	1,150 (19)	14.0	7,293 (95)	26.1
No	4,107 (78)	50.0	11,396 (147)	40.7
Unknown	2,957 (29)	36.0	9,295 (101)	33.2
FEV1.0 ($p = 0.0341$)				
<1 L	61 (1)	0.7	2,744 (33)	9.8
1-2 L	1,999 (25)	24.3	3,957 (50)	14.1
>2 L	1,669 (24)	20.3	926 (15)	3.3
Unknown	4,484 (76)	54.6	20,355 (245)	72.7

[a] Based on the weighted number of patients. [b] Excludes one patient with unknown age.

staging system. Of patients who received surgery, 28% had pathological N2 and 2% had N3 disease. Of the surgically resected tumors, 55.8% were considered R0 (all margins pathologically negative), 17.0% were considered R1 (microscopically positive margins or residual microscopic disease), and 2.0% were considered R2 (gross residual disease or macroscopically positive margins); 25.2% were unknown. The mean number of lymph nodes sampled during resection was 7.8 (range, 0 to 73), and the mean number of lymph nodes positive was 1.57 (range, 0 to 16). Extracapsular nodal extension was noted in specimens from 3.2% of patients.

By definition, all patients in this study had received radiation therapy. Of those who had radiation and surgical resection, 80.4% underwent surgery before radiation, 9.9% after radiation, 9.7% unknown. Of those who had radiation and surgical resection, 46.2% also had chemotherapy: 10.8% preoperatively, 68.3% postoperatively, and 7.7% preoperatively and postoperatively (13.2% unknown). There was no difference in the percentage of patients who received chemotherapy between surgical and non-surgical patients.

The use of surgery was not statistically related to the type of institution at which the patient received radiation treatment: 29.7% of patients at academic institutions, 21.1% at large non-academic institutions, and 17.5% at smaller non-academic institutions underwent surgery.

In a logistic regression analysis, several factors were associated with an increased likelihood of surgery in NSCLC: age <70 years (OR, 5.5; $p = 0.0002$), FEV1 >2 L (OR, 6.4; $p = 0.02$), and N1 disease (OR, 6.7; $p = 0.008$). Race, gender, type of institution, and KPS did not predict surgical intervention.

TABLE 2. Disease characteristics and use of surgery

	Received surgery				Did not receive surgery	
	Clinical stage		Pathological stage		Clinical stage	
Characteristic	Weighted sample size (unweighted)	Percentage[a]	Weighted sample size (unweighted)	Percentage[a]	Weighted sample size (unweighted)	Percentage[a]
Total	8,214 (126)	22.7	8,214 (216)	22.7	27,983 (343)	77.3
Stage						
I	1,312 (15)	16.0	777 (9)	9.5	4,726 (55)	16.9
II	3,083 (39)	37.5	2,952 (41)	35.9	4,284 (47)	15.3
III	3,752 (63)	45.7	3,704 (61)	45.1	17,945 (232)	64.1
Unknown	66 (9)	0.8	780 (15)	9.5	1,027 (9)	3.7
T stage (primary)						
TX	77 (2)	0.9	109 (4)	1.3	505 (7)	1.8
T1	1,530 (20)	18.6	2,240 (23)	27.3	4,222 (47)	15.1
T2	3,391 (45)	41.3	2,156 (41)	26.3	11,152 (132)	39.9
T3	2,116 (31)	25.8	1,912 (30)	23.3	5,564 (63)	19.9
T4	694 (11)	8.4	800 (11)	9.7	4,152 (54)	14.8
Unknown	407 (17)	4.9	997 (17)	12.1	2,388 (40)	8.5
N stage (regional lymph nodes)						
NX	559 (9)	6.8	284 (6)	3.5	4,162 (48)	14.9
N0	2,608 (32)	31.8	1,822 (25)	22.2	6,108 (64)	21.8
N1	2,275 (27)	27.7	2,694 (35)	32.3	2,084 (30)	7.4
N2	2,321 (40)	28.3	2,304 (39)	28.0	11,549 (128)	41.3
N3	45 (1)	0.5	165 (5)	2.0	1,741 (32)	6.2
Unknown	407 (17)	4.9	991 (16)	12.1	2,339 (41)	8.4

[a] Based on the weighted number of patients.

DISCUSSION

This PCS analysis was designed to assess the use of radiation therapy in lung cancer patients, but the results also offer insight into the use of surgery in clinical practice for patients with operable lung cancer treated with radiotherapy. Overall, the patient populations and distribution of histological characteristics are consistent with expected national statistics.[4] Specifically, the breakdown between NSCLC (85.5%) and SCLC (14.5%) has been previously documented.

As expected, the use of surgery was significantly associated with histological characteristics and initial staging. Overall, 19.8% of patients received surgery in addition to radiation as part of their care. Surgery was used much more often in NSCLC patients, which is consistent with SCLC being considered a systemic disease. The relatively low proportion of surgical patients in this PCS probably reflects selection bias. Patients with early stage, surgically curable disease are unlikely to have also received radiation therapy. Similarly, patients with advanced mediastinal disease (N3) or large T4 lesions would have been ineligible for surgery. Indeed, most of the surgical patients assessed in this study had stage I or II disease; a smaller number had stage III disease. Only 2.5% of patients with pathological N3 disease underwent surgical resection; this is consistent with the National Comprehensive Cancer Network (NCCN) recommendation that patients with bilateral mediastinal disease receive chemotherapy and radiation as definitive treatment.[12]

Some patients who had extensive disease were treated with surgery. That probably reflects incomplete preoperative staging workups. In fact, only 2.6% of patients had PET scans, 56.1% had bone scans, and 47.1% had brain scans (CT, MRI, or both) during their evaluation process. This pattern of care will probably change as preoperative workups become more extensive with increased use of PET scanning (which was often not available at the time these patients were diagnosed) and patients are better staged at the initiation of treatment. Most likely, that will upstage the proportion of patients and reduce the use of upfront surgery in this population.

As we anticipated, patients treated with radiation and surgery were younger, had less weight loss, higher KPS, and higher FEV1 value compared with patients treated with radiotherapy alone,. Surgical patients also had more stage I/II (53.5% versus 32.2%; $p = 0.0004$) and less clinical N2/N3 disease (28.8% versus 47.5%; $p = 0.002$) than non-surgical patients. However, there was no significant difference in T stage between surgical and non-surgical patients ($p = 0.26$). In general, T4 disease is considered to be inoperable except for satellite lesions in the same lobe. In the current study, 8.4% patients in the surgical group had T4 disease, compared with 14.8% in the non-surgical group. In some institutions, patients with limited involvement of vertebral body, atria were operated, and postoperative radiotherapy usually followed. Because all of our patients received radiotherapy as

TABLE 3. Characteristics of surgery

Characteristic	Received surgery: Weighted sample size (unweighted)	Percentage[a]
Total	8,214 (126)	22.7
Type of surgery[b]		
Exploration alone (no resection)	910 (17)	11.1
Wedge	481 (13)	5.9
Lobectomy	4,959 (70)	60.4
Bilobectomy	227 (7)	2.8
Pneumonectomy	1,927 (24)	23.5
Unknown	89 (2)	1.1
Extent of resection[c]		
R0	4,023 (70)	55.8
R1	1,228 (12)	17.0
R2	144 (2)	2.0
Unknown	1,820 (23)	25.2
Positive lymph nodes[c]		
0	2,063 (30)	28.6
1-3	3,868 (54)	53.6
4+	800 (14)	11.1
Unknown	484 (9)	6.7

[a] Based on the weighted number of patients. [b] May sum to greater than 100% because of use of more than one technique in a given patient. [c] Based on patients who had a known resection.

part of their treatment, it is quite possible that more advanced T and N stage patients were collected in the current study compared with patients who received surgery alone.

A PCS that analyzed the treatment of NSCLC with all modalities in 1996[10] surveyed a population-based random sample of 898 patients. Only 52% of the patients received the recommended therapy, and race, age, and marital status had profound implications for the correspondence between actual and recommended treatment as defined by the American Society for Clinical Oncology, the National Cancer Institute, and the American College of Chest Surgeons.[11,12] Older, Caucasian, married patients were more likely to receive the recommended therapy. Of the 240 patients with stage I or II disease, 69% underwent lobectomy or pneumonectomy, 10% underwent more limited surgical resection, 16% received radiation alone, and 5% received no therapy. Of those who underwent surgery, 80% received it as definitive therapy alone and 20% as part of combined-modality treatment with chemotherapy, radiation, or both. Patients who underwent the recommended surgery were younger than those who did not. Although the differences did not reach statistical significance, patients who underwent the recommended surgery were also more likely to be non-Hispanic Whites, currently married, without recorded co-morbidity, and current or former smokers.[10] The authors contended that the disparities in care—which corresponded to such non-clinical factors as age, race, co-morbidities, and type of hospital—have been previously recognized[13–16] and may reflect underlying controversies in recommended therapy, access to care, and patient preferences.

In contrast with a previous report,[10] differences in the frequency of surgery did not seem to be related to gender or race in our study. In addition, the likelihood of surgery was not associated with the type or size of facility at which a patient was treated. However, age was a major factor in surgical intervention, despite similarities in co-morbidity between the surgical and nonsurgical groups. That finding may lead to the conclusion that surgery is less likely to be performed on patients older than 70 years regardless of their overall health. Elderly patients without co-morbidities may be adversely affected by this disparity. As the American population ages, a greater proportion of patients will be older than 70 years; if their co-morbidities are not substantially different from that of their younger counterparts, withholding surgery may be difficult to justify.

There are important limitations of this PCS analysis with regard to patterns of surgery in the United States. Specifically, our sampling of patients is limited by the original aim of the study; only radiotherapy facilities were surveyed, and the patients studied were selected according to the use of radiation in their treatment. As a result, the analysis misses a large segment of surgical patients who received definitive treatment without radiation, thereby removing a substantial population of stage I patients from our analysis. In addition, it may be biased toward patients upstaged during surgery, in that such patients are more likely to receive radiation therapy. Indeed, the high proportion of R1 and R2 resections in this population likely reflects this underlying bias. Regardless, radiation and surgery are both key components of multimodality treatment of lung cancer and often are used together.

The role of postoperative radiotherapy in NSCLC remains controversial. The Lung Cancer Study Group (LCSG) conducted a randomized trial to evaluate the role of postoperative radiotherapy alone in patients with completely resected stages II and III epidermoid (squamous cell) NSCLC. The result showed no difference in survival between patients with and without postoperative radiotherapy.[17] However, the patients who received radiotherapy had a significant decrease in local recurrence (1% versus 19% of all patients; $p < 0.05$). In addition, patients with N2 disease seemed to have a disease-free survival benefit from postoperative radiotherapy. The Postoperative Radiation Therapy (PORT) meta-analysis study in 1998 reported that postoperative radiotherapy was detrimental to survival because of increased non-cancer–related mortality.[18] A recent analysis conducted at Memorial Sloan-Kettering Cancer Center showed that this PORT meta-analysis seems to be changing practice patterns, decreasing the application of postoperative radiotherapy. This PORT analysis, however, has been the subject of substantial criticism. First, it included many patients with stage I and II disease for whom there was no clear indication to have postoperative radiotherapy in the first place. Indeed, subgroup analysis in this PORT study showed that the reduced survival only applied to stage I and II, not stage III, disease. Second, many patients in this analysis were treated with poor radiation techniques, including the use of large treatment volumes without CT plan and Cobalt-based irradiation. According to

the PORT analysis, many patients, including patients with stage I and II disease, were treated by pneumonectomy. In this case, postoperative radiotherapy without CT plan can cause unacceptable toxicity to the normal lung and heart. In addition, expansion of the residual contralateral lung shifted the mediastinum after the pneumonectomy. This made it very difficult to irradiate mediastinal lymph node without CT planning. Based on the literature, postoperative radiotherapy is still reasonable for patients with positive margins, N2 disease, and selected N1 disease, such as extracapsular extension, or multiple N1 (hilar) involvement.

Postoperative chemotherapy has recently emerged as a standard treatment option for most patients with resected NSCLC, but the studies justifying its use postdate the current PCS analysis. In 2004, the International Adjuvant Lung Cancer Trial, a large randomized study, showed a 4.1% improvement in 5-year survival for patients who received adjuvant cisplatin-based chemotherapy.[19] In 2005, the National Cancer Institute of Canada trial revealed a 15% improvement in 5-year survival for patients who received adjuvant vinorelbine plus cisplatin in resected stage IB or stage II NSCLC.[20] It is anticipated that adjuvant chemotherapy will be widely accepted and will change the patterns of care for resected NSCLC. However, the best regimen of adjuvant chemotherapy and the optimal sequence of adjuvant chemotherapy with radiotherapy remain unclear. It has been shown that adjuvant concurrent chemoradiation with cisplatin and etoposide has no benefit compared with radiation alone in patients with completely resected stage II and stage III-A NSCLC.[21]

In conclusion, this analysis of data from the original PCS of radiation therapy for lung cancer has elucidated how surgery is being used in facilities throughout the United States. Future studies will undoubtedly address whether new trends in preoperative staging, specifically improvements in diagnostic imaging and the use of PET scans, influence the population of patients undergoing surgery. In addition, improvements in combined modality treatments, the advent of neoadjuvant treatment strategies, and more sophisticated CT-based postoperative radiotherapy will likely affect future recommendations of therapy for this group of operable patients.

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